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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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WENDEROTH, LIND & PONACK, L.L.P.
Suite 800
2033 "K" Street, N.W.
Washington, DC 20006

EXAMINER

CANELLA, KAREN A

ART UNIT PAPER NUMBER

1642

DATE MAILED: 11/20/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/734,002

Applicant(s)
Seiki et al

Examiner
Karen Canella

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-53 is/are pending in the application.
- 4a) Of the above, claim(s) 30-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☒ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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Response to Amendment

1. Please note that the examiner assigned to this application has changed.
2. Claims 14-26 have been canceled. Claims 36-53 have been added. Claims 30-35 remain withdrawn from consideration.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

New Grounds of Rejection

4. Claims 39, 40 and 48 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. There appears to be no difference in the scope of the claim 39, as the genus of antibodies encompassed by claim 36 will not be changed by the origin, (recombinant or natural), of the protein or peptide to which they are directed. There also appears to be no difference in the scope of claim 40 in reference to claim 36 as claim 40 appears to define the activity of the pro-MMP-2 activating factor which would be inherent in the pro-MMP-2 activating factor of claim 36. As such, the antibodies which bind to the matrix metalloproteinase of claim 36 must have the specific embodiment of antibodies which bind to a

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,matrix metalloproteinase which is a pro MMP-2 activating factor, therefore claim 40 appears to encompass the same genus of antibodies as claim 36.

5. Claim 48 recited an intended use for the antibody of claim 44, however, as said intended use is not given patentable weight, claim 48 does not further limit the genus of antibodies encompassed by claim 44. A preamble is generally not accorded any patentable weight where it merely recitesthe intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

6. Claims 46 and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 46 and 47 lack antecedent basis in claims 43 and 36, respectively, because claims 43 and 36 are product claims, whereas claims 46 and 47 are method claims which recite "according to claim 43" and "according to claim 36".

7. Claim 47 provides for the use of the antibody according to claim 36, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

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8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

9. Claims 36-41, 43, 45-47, 49-53 are rejected under 35 U.S.C. 102(a) as being anticipated by Takino et al (Journal of Biological chemistry, Sep 1995, Vol. 270, pp. 23013-23020). Claim 36 is drawn to an isolated antibody which specifically binds the matrix metalloproteinase protein or salt of said protein or partial peptide of said protein, said matrix metalloproteinase protein comprising residues 109-119, 171-178, 229-242 and 533-607 of SEQ ID NO:2, said protein having a maximum molecular weight of approximately 69kDa, wherein said protein is a pro MMP-2 activating factor, and said partial peptide comprises contiguous amino acid residues of SEQ ID NO:2 which are characteristic of said MMP protein. Claim 37 embodies the antibody of claim 36 wherein said protein further comprises residues 564-587 of SEQ ID NO:2. Claim 38 embodies the antibodies of claim 36 wherein said protein comprises SEQ ID NO:2. Claim 39, 40 and 48 appear to be the same as claim 36 and 44 for the reasons set forth in the claim objections

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above. Claim 41 is drawn to the antibody of claim 36 wherein the antibody specifically binds against said partial peptide. Claim 43 specifically embodies monoclonal antibodies. Claim 49 is drawn to the antibody of claim 36, wherein said partial peptide or salt thereof comprises SEQ ID NO:5, 6, 7 or 8. Claim 50 is drawn to the antibody of claim 36, wherein said partial peptide or salt thereof is selected from the group consisting of SEQ ID NO:5, 6, 7 or 8. Claim 51 is drawn to the antibody of claim 36 produced by using a partial peptide selected from the group consisting of SEQ ID NO:5, 6, 7 or 8. Claim 52 specifically embodies the antibody of claim 36 wherein said antibody is not cross-reactive with any one of MMP-1, MMP-2, MMP-3, MMP-7, MMP-8 and MMP-9. Claim 53 embodies the antibody of claim 36 wherein said partial peptide comprises at least 8 contiguous amino acid residues of SEQ ID NO:2 which are characteristic of said MMP protein. Claim 45 is drawn in part to a method for producing the antibody of claim 36 comprising using said partial peptide as an antigen.

Takino et al teach a method of making a monoclonal antibody raised against the peptide of residues 167-181 of MT-MMP-2 which specifically binds the matrix metalloprotein of SEQ ID NO:2 (page 23014, first column, under the heading "Monoclonal Antibodies"). Said residues correspond to SEQ ID NO:6 of the instant application. Examination of Figure 1 indicate all the structural limitations of claims 36, 37, 38, 49 and 50 are present in the disclosed MT-MMP-2. Furthermore, as MT-MMP-2 is identical to the instant SEQ ID NO:2 it would have the inherent activity of converting pro-matrix metalloproteinase 2 from a latent to active form. Takino et al

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disclose that the peptide of residues 167-181 represent a unique insert in MT.-MMP-2, therefore, it is reasonable to conclude that antibodies which were raised to this peptide did not cross react with the other proteins of claim 52.

10. Claims 36-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takino et al (Journal of Biological chemistry, Sep 1995, Vol. 270, pp. 23013-23020) in view of Paul (Fundamental Immunology, (text), 1993, page 460) and Thrope and Rafferty (Preparation and Use of Radio labeled Antibodies and antigens, In: Immunochemistry LabFax, 1994, Kerr and Thrope Ed.s, pages 115-126).. Takino et al teach the specific embodiments of claims 36-41, 43, 45-47, 49-53 for the reasons set forth above. Takino et al do not teach a polyclonal antibody. Paul teaches the advantages of a polyclonal antibody in immunoprecipitations. Takino et al use immunoprecipitation to detect MT-MMP-2 (page 23014, first column, under the heading "Immunoprecipitation"). Takino et al do not teach Radiolabeled antibodies. Thorpe and Rafferty teach Preparation and Use of Radio labeled Antibodies in standard assays for the detection of antigens.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to make a polyclonal antibody to residues 167-181 of SEQ ID NO:2 or to radiolabel the monoclonal antibody taught by Takino et al for use in detecting MT-MMP-2 by the methods taught by Thrope and Rafferty. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of Paul on the

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usefulness of polyclonal antibodies in Immunoprecipitation reactions and the teachings of Thrope and Rafferty on the standard protocols of detecting antigen by means of Radiolabeled antibodies.


11. Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

12. Claims 36, 41, 45, 46 and 53 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the previous office action with regard to “partial peptide(s)”. Applicant has provided new claim 36 which attempts to narrow the scope of said partial peptide by incorporating the limitation of “comprising contiguous antigenic amino acids residues of SEQ ID NO:2 which are characteristic of said MMP protein” and “wherein said partial peptide or salt thereof comprises at least 8 antigenic amino acid residues of SEQ ID NO:2 which are characteristic of said MMP protein”. However, this is insufficient to satisfy the written description requirement because the specification does not teach or provide a number of examples of said residues “which are characteristic of the MMP protein” as to be representative of the genus of proteins claimed.

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13. All other rejection and objections as set forth in Paper No. 10 are withdrawn.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

November 18, 2002